IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

EVERGREEN PHARMACY, INC., Plaintiff, v. MERRICK GARLAND, in his official capacity only as ATTORNEY GENERAL, *et al.*, Defendants.	No. 22-cv-03912 Judge Franklin U. Valderrama

MEMORANDUM OPINION AND ORDER

Plaintiff Evergreen Pharmacy, Inc. (Evergreen) filed suit against Merrick Garland in his official capacity as the Attorney General of the United States, Ann Milgram, in her official capacity as Administrator of the Drug Enforcement Administration, and the United States Drug Enforcement Administration (DEA), (collectively, Defendants), asserting several causes of action stemming from Defendants' Immediate Suspension Order (ISO) suspending Evergreen's DEA Registration. R. 1., Compl.[1] Evergreen now moves the Court pursuant to 21 U.S.C. § 824(d) for an order dissolving the DEA's ISO filed against Evergreen, or, in the alternative, for a temporary restraining order (TRO) against Defendants enjoining the ISO's enforcement pending a final decision on the merits in the ongoing

[1]Citations to the docket are indicated by "R." followed by the docket number and, where necessary, a page or paragraph citation.

administrative proceedings. For the reasons stated below, the Court denies Evergreen's motion.

Background

I. Controlled Substances Act

The Controlled Substances Act (CSA) and its implementing regulations create restrictions on the distribution of controlled substances. 21 U.S.C. §§ 801, *et seq*.; 21 C.F.R. §§ 1300, *et seq*. The CSA requires all persons who dispense controlled substances to obtain a registration from the Attorney General. *See* 21 U.S.C. § 822(a). The Attorney General has delegated this registration authority to the DEA. *See* 28 C.F.R. § 0.100.

These regulations provide that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner." *See* 21 C.F.R. § 1306.06. In addition, the regulations provide that a pharmacist who fills a prescription for a controlled substance has a "corresponding responsibility" to ensure that the prescription was "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *See* 21 C.F.R. § 1306.04.

The DEA "closely observes [registrants] to ensure that their operations are 'consistent with the public interest.'" *Virtus Pharmaceuticals, LLC v. Garland*, 2021 WL 4306165, at *2 (D.D.C. Sept. 22, 2021) (internal citations omitted). For example,

in the case of registered distributors, the DEA determines whether the registrant maintains "effective control[s] against diversion of particular controlled substances." 21 U.S.C. § 823(a)(1), (b)(1). The DEA also considers whether the registrant complies with state and local laws or has any prior criminal convictions related to the possession of controlled substances. *Id.* § 823(a)(2)–(4), (b)(2)–(3). More generally, the CSA directs the DEA to take into account "such other factors as may be relevant to and consistent with the public health and safety." *Id.* § 823(a)(6), (b)(5).

The CSA provides that a registration to dispense a controlled substance may be suspended or revoked upon a finding that the registrant, inter alia, "has committed such acts as would render his registration . . . inconsistent with the public interest . . . ." *See* 21 U.S.C. § 824(a)(4). Before suspending a registration, the DEA must serve upon the registrant an Order to Show Cause (OSC) why the registration "should not be denied, revoked, or suspended." 21 U.S.C. § 824(c)(1)–(2). The registrant is entitled to an administrative hearing before the DEA, conducted pursuant to the Administrative Procedure Act (APA), 5 U.S.C. §§ 551–559, where the Government has the burden of proving that registration is inconsistent with the public interest. *Id.*; *see* 21 C.F.R. §§ 1301.36(d), 13.01.42, 1301.44(e). Following the hearing, the presiding DEA Administrative Law Judge (ALJ) issues a recommendation to the Administrator as to whether the respondent's registration

should be revoked, and the Administrator enters the DEA's final ruling on the ALJ's recommendation. 5 U.S.C. §§ 556(c)(10), 557; 21 C.F.R. § 1301.46.

However, if a registrant poses an "imminent danger to the public health or safety," the CSA authorizes the immediate suspension of the entity's registration. 21 U.S.C. § 824(d)(1). The CSA defines "imminent danger to the public health or safety" to mean "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." 21 U.S.C. § 824(d). The DEA must meet this statutory standard in order to issue an ISO and immediately suspend a registration on an *ex parte* basis. *See* 21 U.S.C. § 824(d)(1).

II. Evergreen Pharmacy

Evergreen is a small family-owned pharmacy which has served the community in Evergreen Park, Illinois since 2008. Compl. ¶ 15.; R. 6-2, Abdallah Aff. ¶¶ 3, 22. Since it opened, Evergreen had been registered with the DEA as a pharmacy to handle controlled substances in Schedules II through V under DEA Certificate of Registration No. FE1057822. Compl. ¶¶ 15–16. Evergreen meets with and builds personal relationships with its patients, as well as provides complimentary home delivery services. *Id.* ¶ 26; Abdallah Aff. ¶¶ 44, 45. Before the issuance of the ISO, approximately 88% of Evergreen's prescription volume was for non-controlled

prescription medication, meaning approximately 12% of its volume was for controlled substances. Compl. ¶ 25; Abdallah Aff. ¶ 33.[2]

III. DEA Investigation

On November 18, 2020, pursuant to an administrative inspection warrant, Defendants conducted an on-site inspection of Evergreen. Compl. ¶ 38; Abdallah Aff. ¶ 10. Defendants obtained and reviewed Evergreen's records and logs of prescriptions dispensed, performed an inventory count of Evergreen's medications in stock, and also performed an inventory reconciliation (meaning Defendants compared Evergreen's records and logs of prescriptions dispensed with the inventory counts of the medications in stock). Compl. ¶ 38; Abdallah Aff. ¶ 10. Included in these logs were records of three patients of interest to the DEA: Patients 1, 2, and 3. Compl. ¶ 39; Abdallah Aff. ¶ 12. Evergreen cooperated and complied with the investigation. Compl. ¶ 40; Abdallah Aff. ¶ 11. On November 20, 2020, a DEA investigator visited Patient 2 and interviewed Patient 2's parents, confirming that the patient was not selling medication and was taking it as prescribed. Abdallah Aff. ¶ 13.

In January 2021, DEA agents interviewed Evergreen's owner and several employees about controlled substance prescriptions dispensed to Patients 1, 2, and 3. Compl. ¶ 41; Abdallah Aff. ¶ 16. Specifically, agents questioned Evergreen's owner about the high quantities of Dilaudid (used to treat pain) dispensed to Patient 2, and the drug combinations dispensed to pharmacy patients, including the controlled

[2]Evergreen's total prescription volume from January 1, 2021 through January 1, 2022 was 73,048 prescriptions. Of that, 8,765 (12%) were controlled substances, and 73,048 (88%) were legend or non-controlled substances. Abdallah Aff. ¶ 33.

substances dispensed to Patients 1 and 3. Abdallah Aff. ¶¶ 16, 17; *see* R. 6-5, Anselmo Aff. ¶ 16. Evergreen's owner's review of pharmacy records show that he spoke to Patient 1, 2, and 3's respective physicians about their diagnoses and/or their prescriptions, and in his professional opinion, each patient had a legitimate medical need for the medications. Abdallah Aff. ¶¶ 16–17.

On May 20, 2021, DEA agents met with Evergreen's owner and provided a report of their concerns related to Evergreen's recordkeeping based on discrepancies identified through the inventory reconciliation performed by the agents. Compl. ¶ 42; Abdallah Aff. ¶ 19. Additionally, the agents had concerns about whether Evergreen was complying with its corresponding responsibility to ensure the controlled substance prescriptions were issued for a legitimate medical purpose, by prescribers who were acting in the ordinary course of medical practice. Abdallah Aff. ¶ 19. After learning of these concerns, Evergreen's owner conducted an inventory reconciliation and provided the DEA with acquisition and dispensing records. Compl ¶ 43; Abdallah Aff. ¶ 20.

On December 17, 2021, the DEA formally began requesting information from Evergreen regarding prescriptions it had filled for twelve patients, including Patients 1, 2 and 3. Compl. ¶ 44; Abdallah Aff. ¶ 21. Subpoenas were issued to Evergreen on December 17, 2021, January 21, 2022, February 14, 2022, and March 4, 2022. Compl. ¶ 44; *see also* Abdallah Aff. ¶ 21. In mid-April 2022, a DEA investigator notified Evergreen's counsel that he was nearing the end of his investigation and once

completed he would discuss the next steps with Evergreen and its counsel. R. 6-1, TRO Memo. at 10.

IV. Immediate Suspension Order and Order to Show Cause

On April 25, 2022, the DEA simultaneously issued the ISO and OSC to Evergreen. R. 1-1, Compl. Exh. A, ISO. The ISO suspended Evergreen's DEA registration after determining that over the course of a two-year period, Evergreen dispensed more than 175 prescriptions to Patients 1, 2, 3, which exhibited "red flags of abuse or diversion." Compl. ¶ 47; ISO at 2. The ISO included allegations regarding the pharmacy's filling of prescription to three patients. For example, with respect to Patient 1, the ISO alleges:

> 13. Between March 13, 2020, and at least February 13, 2022, Evergreen filled numerous controlled substances prescriptions for Patient [1], including: (a) 24 prescriptions for oxycodone; (b) 24 prescriptions for hydrocodone; and (c) six prescriptions for amphetamine, a Schedule II Controlled Substance.
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> 14. All of these above-listed prescriptions were dispensed outside the usual course of professional practice for the State of Illinois in violation of federal and state law. *See* 21 C.F.R. § 1306.06; 720 Ill. Comp. Stat. Ann § 570/312. In particular, Evergreen failed to resolve red flags of abuse or diversion and dispensed high-dose opioids without resolving why the dosage was so high, or determining what Patient [1] was being treated for, and what the treatment plan was. Evergreen also filled amphetamine prescriptions for Patient [1], which served to increase the risk that Patient [1] would divert controlled substances without any resolution by Evergreen. Finally, Evergreen failed to maintain a patient profile for Patient [1], in violation 7 of Ill. Adm. Code § 1330.700.

ISO at 4. The ISO further explained that the DEA had "retained an independent pharmacy expert to review (among other materials) Evergreen's dispensing records for Patients [1, 2, and 3]." *Id.* The DEA's pharmacy expert concluded that, "[b]ased on Evergreen's numerous deviations from the standard of care in issuing prescriptions

for controlled substances," Evergreen's actions "fell below the minimal standards applicable to the practice of pharmacy in Illinois." *Id.* In addition, the ISO alleges that Evergreen had "continued to unlawfully dispense controlled substances to [Patients 1, 2, and 3], including as recently as February 13, 2022. Evergreen's ongoing dispensing of dangerous opioids outside the usual course of professional practice poses an 'imminent danger' within the meaning of 21 U.S.C. § 824(d)." *Id.* at 4.

The ISO concluded with the Administrator's findings. Compl. ¶ 48; ISO at 4. First, "Evergreen's continued registration is inconsistent with the public interest," pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4). Compl. ¶ 48; ISO at 4. Second, "on numerous occasions, Evergreen issued prescriptions outside the usual course of professional practice and not for a legitimate medical purpose, which is inconsistent with the public interest." ISO at 4. Third, "in light of the rampant and deadly problem of prescription controlled substance abuse . . . Evergreen's continued registration during the pendency of these proceedings would constitute 'an imminent danger to the public health or safety' because of the substantial likelihood of an imminent threat that death, serious bodily harm, or abuse of controlled substances will occur in the absence of this suspension." *Id.* at 4–5.

On May 5, 2022, Evergreen filed a request for hearing with an ALJ. R. 12, Resp. Exh. 2 at 1. The next day, the ALJ ordered the DEA to file a prehearing statement by May 20, 2022, and for Evergreen to file a prehearing statement by June 6, 2022. *Id.* at 1–2. The ALJ scheduled a prehearing conference by video for June 7, 2022, with a hearing scheduled for July 12, 2022. *Id.* at 3. On the day its statement

was due, Evergreen requested 30 days to submit an amended prehearing statement. R. 12, Resp. Exh. 5 at 3. The ALJ granted Evergreen's request and ordered the parties to file any additional supplemental prehearing statements, to include witness summaries by July 25, 2022. *Id.* at 3–5. The ALJ reset the hearing scheduled for July 12, 2022 to September 6, 2022. *Id.* at 7.

On June 17, 2022, Evergreen filed a motion with the ALJ for the issuance of subpoenas for patient medical files to medical providers and for the personnel records of the DEA witnesses. R. 12, Resp. Exh. 6 at 1. The ALJ denied Evergreen's motion without prejudice, explaining that discovery was not generally allowed in administrative hearings under the APA. *Id.* at 2–5, 7.

On July 27, 2022, Evergreen filed the instant suit against Defendants seeking to set aside the DEA's immediate suspension of Evergreen's controlled substance registration while the administrative proceedings are still pending. Compl. The Complaint asserts five counts stemming from Defendants' issuance of the ISO. *Id.* Count I alleges that the DEA improperly issued the ISO against Evergreen in the absence of a substantial likelihood of any immediate threat as required by 21 U.S.C. § 824(d). *Id.* ¶¶ 60–65. Count II alleges that Defendants were not statutorily authorized to issue the ISO pursuant to 21 U.S.C. § 824(d) and, as a result, the ISO exceeds Defendants' statutory jurisdiction. *Id.* ¶¶ 66–73. Count III alleges that Defendants' decision to issue the ISO was arbitrary and capricious. *Id.* ¶¶ 74–82. Count IV alleges that the ISO was issued without observing procedure required by law under 5 U.S.C. § 706(2)(D). *Id.* ¶¶ 83–88. Finally, Count V alleges that the ISO

deprived Evergreen of due process and impaired its property interest because the ISO denied Evergreen prior notice of the allegations against it and the opportunity to be heard and dispute the ISO's allegations. *Id.* ¶¶ 89–94

On July 28, 2022, Evergreen filed the instant emergency motion to dissolve the DEA's ISO or, in the alternative, for a temporary restraining order. TRO Memo. On August 1, 2022, Defendants filed their response in opposition including Defendants' and Evergreen's prehearing statement to the ALJ as exhibits to their response. Resp.; R. 12 at 30–63.[3] The Court found that Evergreen's motion did not present an emergency as required for issuance of a TRO under Rule 65(b), and as such construed Evergreen's alternative request for a TRO as an alternative request for a preliminary injunction. R. 13, 8/4/2022 Order (citing *Levas and Levas v. Village of Antioch, Ill.*, 684 F.2d 446, 448 (7th Cir. 1982)).

On August 8, 2022, the Court held a hearing at which it heard argument from the parties. R. 16.; Mot. Hearing. At the hearing, Defendants did not contest the facts that were offered by Evergreen. *Id.*

Legal Standard

The legal standard employed for a temporary restraining order is the same as one for a preliminary injunction. *Mays v. Dart*, 453 F. Supp. 3d 1074, 1087 (N.D. Ill. 2020) (citations omitted). "A preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries

[3]The parties' "prehearing statements" are part of the administrative record and as such can be properly considered by the Court in determining whether the DEA's issuance of the ISO was arbitrary and capricious. *See Cardinal Health*, 846 F. Supp. 2d at 215.

the burden of persuasion." *Goodman v. Illinois Dept. of Financial and Professional Regulation*, 430 F.3d 432, 437 (7th Cir. 2005) (internal quotation marks and citation omitted) (emphasis in original). To succeed, the movant must demonstrate (i) a likelihood of success on the merits, (ii) that it has no adequate remedy at law, and (iii) that it will suffer irreparable harm if the relief is not granted. *Mays v. Dart*, 974 F.3d 810, 818 (7th Cir. 2020) (internal citations omitted).

If the moving party meets this three-element threshold showing, the court "must weigh the harm that the plaintiff will suffer absent an injunction against the harm to the defendant from an injunction." *GEFT Outdoors, LLC v. City of Westfield*, 922 F.3d 357, 364 (7th Cir. 2019) (quoting *Planned Parenthood, of Ind. & Ky., Inc. v. Comm'r of Ind. State Dep't of Health*, 896 F.3d 809, 816 (7th Cir. 2018)). "Specifically, the court weighs the irreparable harm that the moving party would endure without the protection of the preliminary injunction against any irreparable harm the nonmoving party would suffer if the court were to grant the requested relief." *Girl Scouts of Manitou Council, Inc. v. Girl Scouts of the U.S.A., Inc.*, 549 F.3d 1079, 1086 (7th Cir. 2008) (citing *Abbott Labs. v Mead Johnson & Co.*, 971 F.2d 6, 11–12 (7th Cir. 1992)).

The Seventh Circuit has described this balancing test as a "sliding scale": "if a plaintiff is more likely to win, the balance of harms can weigh less heavily in its favor, but the less likely a plaintiff is to win[,] the more that balance would need to weigh in its favor." *GEFT Outdoors*, 992 F.3d at 364 (citing *Planned Parenthood*, 896 F.3d at 816). Finally, the court must consider the interests of non-parties in granting

or denying the requested relief. *Ty, Inc., v. Jones Grp., Inc.*, 237 F.3d 891, 895 (7th Cir. 2001).

"The court may deny [the movant's] request for a preliminary injunction without a hearing if it concludes as a matter of law that [the movant's] allegations, even if proven, are insufficient to support the issuance of a preliminary injunction." *Piekosz-Murphy v. Bd. of Educ. of Cmty. High Sch. Dist. No. 230*, 858 F. Supp. 2d 952, 961–62 (N.D. Ill. 2012) (citing *Schlosser v. Commonwealth Edison Co.*, 250 F.2d 478, 480–81 (7th Cir.1958); 11A Charles A. Wright et al., Federal Practice & Procedure § 2949; 13 James Wm. Moore et al., Moore's Federal Practice—Civil § 65.21).

Analysis

Evergreen advances two arguments seeking dissolution or suspension of the ISO. First, Evergreen contends that 21 U.S.C. § 824(d) authorizes the Court to dissolve an improperly issued ISO. TRO Memo. at 1. Second, in the alternative, Evergreen urges the Court to issue a TRO under Rule 65(a) enjoining the DEA from enforcing the ISO pending a final decision on the merits in the administrative proceeding. *Id.*

As discussed above, the CSA requires all persons who dispense controlled substances to obtain a registration from the Attorney General. *See* 21 U.S.C. § 822(a). "The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety." *Id.* § 824(d)(1). The term "imminent danger to the public health or safety" means "that

due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this subchapter or subchapter II, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." *Id.* § 824(d)(2).

The issuance of an ISO is made reviewable by a court of competent jurisdiction under 21 U.S.C. § 824(d)(1). *Medical Pharmacy Inc. v United States Drug Enforcement*, 2020 WL 8679978, at *2 (M.D. La Jul. 3, 2020). As courts have recognized, the arbitrary and capricious standard of review applies to APA claims challenging the issuance of an ISO under 21 U.S.C. § 824(d). *See Novelty Distributors, Inc., v. Leonhart*, 562 F. Supp. 2d 20, 29 (D.D.C. 2008) ("The underlying question on the merits is whether DEA acted arbitrarily and capriciously in suspending [the plaintiff's] registration based on a preliminary finding that its continued operation posed an 'imminent danger to public health and safety'"); *Keysource Med., Inc. v. Holder*, 2011 WL 3608097, at *6 (S.D. Ohio Aug. 16, 2011); *United Prescription Servs., Inc. v. Gonzalez*, 2007 WL 1526654, at *2 (M.D. Fla May 23, 2007) (collecting cases).

An agency's determination is arbitrary and capricious if it relied on factors Congress did not intend to consider, offers explanations for its actions that run "counter to the evidence before the agency" rendered a decision that "is so implausible that it could not be ascribed to a difference in view or the product of the agency expertise," or "entirely failed to consider an important aspect of the problem." *See Zero Zone, Inc. v. United States Dep't of Energy*, 832 F.3d 654, 668 (7th Cir. 2016)

(citation omitted); *see also Sierra Club v. Marita*, 46 F.3d 606, 619 (7th Cir. 1995). Under this standard, judicial review is deferential and "a court may not substitute its own policy judgment for that of the agency." *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021).

I. Motion to Dissolve the ISO

Evergreen argues that the Court has authority to dissolve the ISO issued by the DEA. TRO Memo. at 11. Evergreen asks the Court to hold a hearing to decide *de novo* whether the facts support that the DEA has issued the ISO based on a showing of "imminent danger" as evidenced by "a substantial likelihood of an immediate threat of death, serious bodily harm, or abuse of a controlled substance [that] will occur in the absence of an immediate suspension of the registration." *Id.* at 11–12. Evergreen maintains that the DEA has failed to show an imminent danger to public health or safety. *Id.* at 12–19.

Defendants respond that federal courts reviewing requests for relief from a DEA-issued ISO under 21 U.S.C. § 824(d) have generally followed the standard of review for temporary restraining orders or preliminary injunctions. Resp. at 7. Moreover, any review of the DEA's issuance of an ISO is, according to Defendants, reviewed under an arbitrary and capricious standard. *Id.* (citing *Novelty Distributors*, 562 F. Supp. 2d at 29; *Cardinal Health, Inc v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012) (collecting cases).

Initially, as Evergreen concedes, the Seventh Circuit has not had the occasion to interpret an ISO challenge under 21 U.S.C. § 824(d). TRO Memo at 13 n.8; Mot.

Hearing. Instead, Evergreen relies on an out-of-Circuit case, *Oak Hill Hometown Pharmacy v. Dhillon*, 418 F. Supp. 3d 124, 128 (S.D. W. Va. 2019), for the proposition that the Court should review the administrative record under a *de novo* standard of review in assessing the ISO. TRO Memo. at 11–12. Defendants point out—and Evergreen acknowledges—that *Oak Hill* has been criticized by other courts for failing to analyze § 824(d) motions under the proper standard for injunctive relief and for improperly shifting the burden of proof from the movant to the DEA. Resp. 7–8; TRO Memo. at 13 n.8. The Court agrees with Defendants.

In *Oak Hill Hometown Pharmacy*, the court addressed a challenge to an issuance of an ISO under 21 U.S.C. § 824(d). 418 F.3d at 128. There, the plaintiff pharmacy requested a temporary restraining order regarding an ISO. *Id.* at 128. The court determined that 21 U.S.C. § 824(d)'s statutory authority grant made it more appropriate to consider the motion as a "motion to dissolve the ISO." *Id.* The court applied a *de novo* review standard instead of viewing the challenge under the more stringent injunctive relief standard. *Id.* The court found that the lack of factfinding procedures in administrative process regarding the ISO, coupled with the statutory authority under 21 U.S.C. § 824(d)(1) to review the ISO, permitted the court to engage in *de novo* review. *Id.* at 128–29.

However, before and since *Oak Hill* was issued, the majority of federal courts have handled challenges to a DEA-issued ISO through motions for injunctive relief. *See, e.g.*, *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 823–24 (5th Cir. 1976);

Cardinal Health, 846 F. Supp. 2d at 210 (D.D.C. 2012); *Aarric*, 2020 WL 211460, at *2 (collecting cases).

As the court observed in *Aarric*, the *Oak Hill* approach "leaves courts without a legal standard to guide the analysis. It also goes against otherwise unanimous federal courts that considered these challenges as requests for TROs or preliminary injunctions." 2020 WL 211460, at *2. Furthermore, applying a *de novo* approach here, with respect to the issuance of the ISO is inconsistent with the Court's scope of review of APA claims. 5 U.S.C. § 706. The Court sees no reason to set aside the fundamental doctrines of administrative review under the arbitrary and capricious standard to apply *de novo* review examination to an agency's action. *See Episilon Elecs., Inc. v. U.S. Dep't of Treasury*, 857 F.3d 913, 919 (D.C. Cir. 2017) (noting that *de novo* review in APA cases is extraordinary and rare, so rare that it has never been done in the D.C. Circuit). Therefore, the Court will not depart from the majority view, and will evaluate Evergreen's motion as one for injunctive relief. Having decided that the TRO/preliminary junction standard governs, the Court denies Evergreen's motion to dissolve the ISO pursuant to the *Oak Hill* case and turns to considering Evergreen's alternative request for a temporary restraining order. As discussed above, the Court construes Evergreen's alternative request for a TRO as an alternative request for a preliminary injunction. *See Levas*, 684 F.2d at 448.

II. Preliminary Injunction

Evergreen maintains that it is entitled to injunctive relief because: (1) Evergreen is likely to succeed on the merits of its claim because the facts do not

support the DEA's issuance of the ISO in that there is no "imminent danger to the public health or safety" evidenced by "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance [that] will occur in the absence of an immediate suspension of the registration"; (2) Evergreen and its patients will suffer irreparable harm if enforcement of the ISO is not enjoined because Evergreen likely will go out of business before there is a decision on the merits in the administrative proceeding; (3) Evergreen has no adequate remedy at law, since the enforcement of the ISO is causing it lost revenue, harm to reputation and goodwill, and loss of third-party insurance providers, and the DEA has sovereign immunity so Evergreen cannot recover monetary damages from it; and (4) the balance of hardships and the public interest strongly weigh in favor of Evergreen having a viable DEA registration. TRO Memo. at 21–30. The Court begins with the first element, the likelihood of success on the merits.

Evergreen contends that its burden on the success of the merits is met if Evergreen can show that it has a "better than negligible chance of succeeding on the merits." TRO Memo. at 21 (citing *Meridian Mut. Ins. Co. v. Meridian Ins. Group*, 128 F.3d 1111, 1114 (7th Cir. 1997); *Green River Bottling Co. v. Green River Corp.*, 997 F.2d 359, 361 (7th Cir. 1993)). However, the "better than negligible chance" standard no longer controls. Recently, the Seventh Circuit explained that a "possibility of success is not enough" and "[n]either is a better than negligible chance." *Illinois Republican Party v. Pritzker*, 973 F.3d 760, 762 (7th Cir. 2020) (internal quotation marks and citations omitted). Still, while the moving party bears a "significant

burden," the moving party "need not show that it definitely will win the case." *Id.* at 763. The requisite "strong showing" of a likelihood of success on the merits does not require proof by a preponderance of the evidence, but it does "normally include [] a demonstration of how the applicant proposes to prove the key elements of its case." *Id.* (internal citations and quotations omitted).

Evergreen maintains that it will likely succeed on the merits, advancing two core arguments: (1) the facts do not support the DEA's issuance of the ISO; (2) the DEA's conduct and its issuance of the ISO constitutes arbitrary and capricious conduct. TRO Memo at 21–24.

In response, Defendants argue that: (1) Evergreen cannot show that the DEA issued the ISO without a showing of imminent harm as required by 21 U.S.C. § 824, or that the ISO was issued without adequate notice or unduly delayed following the DEA's execution of the administrative inspect warrant upon Evergreen in November 2020; (2) Evergreen provides no evidence to show that the DEA's ISO was arbitrary and capricious; and (3) Evergreen will not be able to retrieve its controlled substances placed under seal after the ISO took effect because such a request is outside the scope of judicial review.[4] Resp. at 9–11.

As a preliminary matter, Evergreen incorporates into its argument in support of a likelihood of success on the merits its earlier argument that asks this Court to use its "express authority" to dissolve the ISO by contending that there is no

[4]Although Evergreen does not argue this position in its TRO memorandum, it does ask that Defendants immediately return or unseal controlled substances that it may have seized or placed under seal in connection to the ISO in its request for relief. TRO Memo. at 31.

"imminent danger to the public health or safety" evidenced "by a substantial likelihood of an immediate threat that death, serious bodily harm or abuse of a controlled substance that will occur in the absence of an immediate suspension of the registration." TRO Memo at 21–22. As discussed above, such an analysis is not one that the Court conducts *de novo*. *See supra* Section I. Since this is a decision of a federal agency, the Court applies the arbitrary and capricious standard. *See Novelty Distributors*, 562 F. Supp. 2d at 29 ("The underlying question on the merits is whether DEA acted arbitrarily and capriciously in suspending [the plaintiff's] registration based on a preliminary finding that its continued operation posed an 'imminent danger to public health or safety.'"). The Court reiterates that judicial review under the arbitrary and capricious standard is deferential, and the Court will not substitute its own policy judgment for that of the DEA. *Prometheus Radio Project*, 141 S. Ct. at 1158.

To meet the first element for injunctive relief, Evergreen must prove that it is likely to succeed in showing the Court that the DEA's initial decision to issue the ISO was arbitrary and capricious. *George Pharmacy*, 2019 WL 7423550, at *2 (citing *Novelty Distributors*, 562 F. Supp. 2d at 29).

"[I]n applying the APA's arbitrary and capricious standard, 'the focal point for judicial review must be the administrative record already in existence, not some new record made initially in the reviewing court.'" *Cardinal Health*, 846 F. Supp. 2d at 215 (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam)). Under this standard, the Court is limited to considering whether the DEA articulated a rational

connection between the facts found and the decision made. *Medical Pharmacy Inc.,* 2020 WL 8679978, at *2 (citations omitted). Ultimately, "[Evergreen] must show that it has a likelihood of success in proving that in light of the information before the DEA at the time of the ISO, the DEA acted arbitrarily and capriciously in issuing the ISO." *George Pharmacy,* 2019 WL 7423550, at *2.

As mentioned above, the CSA defines "imminent danger to the public health or safety" to mean, "that due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant . . . there is *a substantial likelihood* of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." *Id.* § 824(d)(2) (emphasis added).

In the brief as well as at the motion hearing, Evergreen insists that the 2016 amendment to the CSA, which added the aforementioned definition of "imminent danger to the public health or safety" *heightened* the statutory standard. TRO Memo at 6 (emphasis added). Before the 2016 amendment, the CSA did not include any definition of the term. *See* 21 U.S.C. § 824 (eff. Oct. 17, 2000–Apr. 18, 2016). Evergreen posits that the ISO does not show that any patient actually abused or diverted a controlled substance or was otherwise harmed by the prescriptions filled at the pharmacy. TRO Memo. at 21. Evergreen submits that the imminent danger standard requires *concrete* evidence that the Pharmacy was filling prescriptions that patients were abusing or diverting at the time the agency issued the ISO. TRO Memo.

at 19, 21 (citing *Oak Hill Hometown Pharmacy*, 418 F. Supp. at 131) (emphasis added).

Evergreen's argument is misplaced for several reasons. First, the added definition is instructive, but it does not make a difference here. Since the 2016 amendment, courts have continued to look to pre-2016 cases for guidance in determining whether the DEA was arbitrary and capricious in finding of imminent harm, *see George Pharmacy*, 2019 WL 7423550, at *4 (citing *United Prescription Servs.*, 2007 WL 1526654, at *3 *Keysource Med.*, 2011 WL 3608097, at *8), and have not required *actual* harm to satisfy the standard, *see id.*; *Med. Pharmacy*, 2020 WL 8679978, at *2–4. According to those pre-amendment cases, the relevant inquiry is whether Evergreen's infractions demonstrate a pattern and practice of conduct which the DEA could reasonably conclude was inconsistent with public health and safety if so then the ISO is not arbitrary and capricious. *See George Pharmacy*, 2019 WL 7423550, at *4. (internal quotation and citations omitted). Second, Evergreen misreads *Oak Hill*. There is no language in *Oak Hill* that states that the imminent danger standard requires *concrete* evidence for the government to meet its burden with respect to issuing an ISO. (emphasis added). With this framework in mind, the Court turns to whether the DEA articulated a rational connection between the facts found and the decision made.

To begin, Defendants' prehearing statement notes that the diversion investigator had served Evergreen a series of administrative subpoenas and Evergreen produced, prescription copies (including fill labels), and dispensing logs for

Patients 1, 2, and 3. and patient profiles for Patients 2 and 3. The investigator then turned over a copy of these documents along with documents from the Illinois Prescription Monitoring Program database to the DEA's pharmacy expert. Resp. at Exh. 6. at 16. After reviewing the documents, the DEA's pharmacy expert determined that Evergreen repeatedly filled prescriptions without resolving the red flag of dangerous drug combinations for Patients 2 and 3 which is beneath the standard of care and outside the usual course of professional practice and in violation of the Evergreen's pharmacist corresponding responsibilities. *Id.* at 19. Such dangerous combinations are widely known to be abused or diverted which significantly increase a patients risk of morbidity or overdose. *Id.* at 18.

The DEA pharmacy expert further found that the prescriptions issued to Patients 1, 2, and 3 and filled by Evergreen, reflected a pattern of prescribing an unusual number of prescriptions for commonly abused or diverted drugs and frequently issued prescriptions for such drugs in high dosages. *Id.* at 20. This conduct raised a red flag that must be resolved (and documented) prior to dispensing and Evergreen did not adequately document the resolution of this red flag for Patients 1, 2 and 3. *Id.* at 21. In addition, the DEA pharmacy expert found that a patient receiving concurrent prescriptions for two drugs in the same class, such as two short-acting opioids—e.g., hydromorphone and morphine—is also a red flag of abuse or diversion and considered "therapeutic duplication." *Id.* The DEA's pharmacy expert noted that where a pharmacy like Evergreen has observed therapeutic duplication, this is a red flag of abuse or diversion, and gives the pharmacy reason to suspect that

the prescriber may not be prescribing such drugs for a legitimate medical purpose and within the usual course of professional practice. Resp. at Exh. 6. at 21. Based on the investigation and independent review by the pharmacy expert, the DEA issued the ISO. ISO at 1–6.

Here, as stated in the ISO, the DEA had found and concluded that Evergreen dispensed large quantities of opioids and other controlled substances in dangerous combinations from as early as February 2020 until as recently as February 13, 2022. ISO at 3–4.

For instance, between March 13, 2020, to February 13, 2022, Evergreen filled numerous prescriptions for Patient 1, including: (a) 24 prescriptions for oxycodone; (b) 24 prescriptions for hydrocodone; and (c) six prescriptions for amphetamine. ISO at 4. Significantly, Evergreen does not dispute that it dispensed these large quantities of opioids and other controlled substances. TRO Memo. at 22. The DEA stated in the ISO that the amphetamine prescriptions alone "served to increase the risk that Patient 1 would divert controlled substances without any resolution by Evergreen." ISO at 4. Additionally, Evergreen failed to maintain a patient profile for Patient 1. *Id.* As detailed in the ISO, the DEA provides two more examples of Evergreen's conduct of filling numerous controlled substances prescriptions for Patients 2 and 3. *Id.* at 3–4.

The DEA found that between March 2, 2020, and February 2, 2022, Evergreen filled numerous controlled substances prescriptions for Patient [2], including: (a) 24 prescriptions for hydromorphone, a Schedule II Controlled Substance; (b) 13

prescriptions for morphine sulfate, a Schedule II Controlled Substance; (c) 25 prescriptions for clonazepam, a Schedule IV Controlled Substance; (d) one prescription for hydrocodone, a Schedule II Controlled; and (e) one prescription for methadone, a Schedule II Controlled Substance. ISO at 3.

Moreover, the DEA found that between February 24, 2020, and at least February 8, 2022, Evergreen filled numerous controlled substances for Patient [3], including: (a) 24 prescriptions for hydrocodone; (b) 21 prescriptions for tramadol, a Schedule IV Controlled Substance; (c) 13 prescriptions for lorazepam, a Schedule IV Controlled Substance; and (d) three prescriptions for Belbuca, a brand name for buprenorphine, a Schedule III Controlled Substance. *Id.* The DEA determined that Evergreen failed to resolve red flags of abuse or diversion and dispensed high-dose opioids without resolving why the dosage was so high or determining the course of treatment for Patient [2] and [3]. *Id.* at 3–4.

Furthermore, Evergreen is a retail pharmacy dispensing controlled substances directly to its customers. Compl. ¶¶ 15–16. As such, it has a "corresponding responsibility" to ensure the proper prescribing and dispensing of controlled substances to patients. 21 C.F.R. § 1306.04(a). As the ISO indicated, the listed prescriptions were dispensed outside the usual course of professional practice for the State of Illinois in violation of federal and state law, which supports the DEA's conclusion that Evergreen's continued operation posed an imminent danger to public health or safety. *See* 21 C.F.R. § 1306.06; 720 Ill. Comp. Stat. Ann. § 570/312. ISO at 3–4. *See Akhtar-Zaidi v. Drug Enforcement Administration*, 841 F.3d 707, 713 (6th

Cir. 2016) (finding that a failure to comply with state and federal laws concerning the dispensing of controlled substances can create a substantial likelihood that abuse of controlled substances would occur in the absence of an immediate suspension). In summary, the DEA's review of Patient 1, 2, and 3's files demonstrated that Evergreen had dispensed large quantities of controlled substances in dangerous combinations over the course of fourteen months which shows a "substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." *see* 21 U.S.C. § 824(d)(2); ISO at 2–4. Taken together, this indicates that Evergreen's infractions demonstrate a pattern and practice of conduct which the DEA could reasonably conclude was inconsistent with public health and safety. *See George Pharmacy*, 2019 WL 7423550, at *4. (internal quotation and citations omitted).

Next, Evergreen contends that the DEA's delay of over a year and a half to investigate Evergreen, and to only identify three patients across the many hundreds it serves constitutes arbitrary and capricious conduct by the DEA. TRO Memo. at 21 (citing *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822 (5th Cir. 1976).

At the hearing, Defendants pointed out that Evergreen's argument claiming that it was prejudiced by the delay is at odds with its contention it suffers irreparable harm because during the interim between the initial investigation and the ISO, Evergreen was able to prescribe controlled substances to its patients. Mot. Hearing. More importantly, however, during the investigation Evergreen and Defendants were actively in discussions and exchanging information. *Id.* Even during these

discussions Evergreen was still prescribing the dangerous combination of drugs in quantities that could kill Patients 1, 2, and 3. *Id.*

Norman Bridge, is inapposite to the present case. In *Norman Bridge*, the DEA's ISO was based on the company's president's guilty plea for dispensing a controlled substance seven months earlier and record keeping violations. *Id.* at 823. In light of the seventh month delay, the district court issued a restraining order because it found that the plaintiff's business did not pose an imminent danger to public health. *Id.* at 826. The former Fifth Circuit upheld the preliminary injunction. *Id.* at 827-829. In doing so, it focused on whether the DEA had demonstrated an imminent harm to the public as required by the statute in effect at the time and determined that the district court's finding of no imminent danger was not clearly erroneous. *Id.* at 829.

Here unlike *Norman Bridge*, the DEA's delay for issuing the ISO is justified for several reasons. First, during this timeframe Evergreen and Defendants exchanged information and were in frequent communication. Second, all throughout this process Evergreen continued dispensing dangerous combinations of controlled substances to Patients 1, 2, and 3 in large quantities, thus, continuously posing an imminent danger to the public health or safety. Third, although not raised by the parties, a delay of fourteen months against the backdrop of an unprecedented pandemic is reasonable given the uncertainty of the situation. *See United Prescription Services,* 2007 WL 1526654 *4 (finding that any claimed delay between the execution of an administrative inspection warrant and the issuance of the ISO

was reasonable given the pendency of negotiations between the pharmacy and the DEA during an ongoing investigation prior to the issuance of the ISO).

Based on the administrative record before the Court, the Court finds the DEA examined the relevant data and articulated a rational connection between the facts found and the decision made. *See WorldTravelService v. United States*, 49 Fed. Cl. 431, 441 (2001) (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). That is, the DEA reviewed numerous records, including prescription copies, dispensing logs, and patient profiles. The DEA consulted a pharmacy expert to review those records, who determined that Evergreen repeatedly filled prescriptions without resolving various red flags with respect to the prescriptions for those patients, such as a dangerous combination of drugs or a large quantity of drugs. The pharmacy expert therefore concluded that Evergreen's filling of prescriptions for Patients 1, 2, and 3 fell below the minimal standards applicable to the practice of pharmacy in Illinois. The DEA administrator therefore concluded based on the findings spelled out in the ISO and the pharmacy expert's conclusions, that "in light of the rampant and deadly problem of prescription controlled substance abuse," Evergreen's continued registration would constitute an imminent danger to the public health or safety "because of the substantial likelihood of an imminent threat that death, serious bodily harm, or abuse of controlled substances will occur in the absence of suspension." ISO at 4–5.

The Court therefore finds that the DEA has rationally connected the pertinent facts to its conclusion that there was imminent harm justifying an ISO. *See George*

Pharmacy, 2019 WL 7423550, at *2 (finding that the repeated dispensing of the combinations opioids, benzodiazepines, and muscle relaxants that create an effect similar to heroin—that can be fatal—to two pharmacy patients posed an imminent danger to public health or safety); *see also Keysource Med.*, 2011 WL 3608097, at *8 ("The risk of continued distribution of controlled substances without adequate controls against diversion is imminent harm, as it poses danger to substance abusers and the public as a whole if [the registrant] were allowed to continue dispensing/diverting large quantities of controlled substances during the pendency of the administrative hearing." (quotations omitted)).

Lastly, Defendants point out that Evergreen cannot retrieve any controlled substances held pursuant to the ISO. Resp. at 11. The Court agrees. The CSA expressly states that "[n]o disposition may be made of any controlled substances . . . under seal until the time for taking an appeal has elapsed or until all appeals have concluded." 21 U.S.C. § 824(f); *see also Virtus Pharmaceuticals*, 2021 WL 4306165, at *9. As indicated in the parties' briefs, the administrative proceeding related to the ISO has yet to conclude. Absent a conclusion of an appeal, the DEA does not have the statutory authority to release any controlled substances held pursuant to the ISO.

Additionally, the DEA's decision to place drugs under seal after the issuance of the ISO is within the DEA's discretion. *See* 21 U.S.C. § 824(f) (noting that where the DEA suspends a registration "all controlled substances . . . owned or possessed by the [suspended] registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion

of the [DEA], be placed under seal."). As it stands, the decision to retain drugs under seal during the pendency of an administrative proceeding falls within the purview of the DEA's discretion, and as such, is excluded from judicial review under the APA. *See Virtus Pharmaceuticals,* 2021 WL 4306165 *9.

All things considered, Evergreen's arguments boil down to a matter of weight—i.e., the DEA did not have enough evidence of actual abuse or diversion to show that there was an immediate harm to the public interest. But under the arbitrary and capricious standard, the Court is limited to considering whether the DEA had a mere rational connection from the facts to its decision. Evergreen has failed to show that it could succeed in proving that the DEA lacked such a rational articulation in this case. Although the DEA's administrative record is thin and may be found inadequate at a later administrative hearing; at this juncture, Evergreen has failed to demonstrate that it is likely to succeed in showing that the DEA's initial decision to issue the ISO. *See Zero Zone, Inc.,* 832 F.3d at 668.

Accordingly, at this stage, even if all of Evergreen's allegations were proven, based on the evidence before the DEA at the time of the issuance of the ISO, the Court cannot find that Evergreen has met its burden to show it is likely to succeed on the merits.

Since Evergreen cannot show likelihood of succeeding on the merits, the Court need not go any further with respect to Evergreen's motion. *See AM Gen Corp. v. DamilerChrysler Corp.*, 311 F.3d 796, 830 (7th Cir. 2002) ("[N]o likelihood of success on the merits is reason enough to deny the motion for [temporary restraining order]

without further discussion.") (citations omitted); *see also Piekosz-*, 858 F. Supp. 2d at 961–62 (declining to address the remaining elements of a preliminary injunction because the plaintiff failed to demonstrate a reasonable likelihood of prevailing on the merits of the underlying claim); *Stone v. Bd. of Elections Comm'rs for the City of Chi.*, 2011 WL 66040, *7 (N.D. Ill. Jan. 10, 2011) (same).

Conclusion

For the foregoing reasons, the Court denies Evergreen's instant emergency motion to dissolve the DEA's ISO or, in the alternative, for a temporary restraining order [5]. Defendants are directed to answer the Complaint or otherwise plead by August 31, 2022. The Parties are to file a joint status report discussing next steps by September 13, 2022.

DATED: August 11, 2022

United States District Judge
Franklin U. Valderrama